DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M 3382n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

April 30, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 30-9

M & P Dairy
9430 W. Kleck Rd.
Casa Grande, AZ 85222

Attention: Michael H. Dugan, Owner

Dear Mr. Dugan,

An investigation at your dairy operation located at 9430 W. Kleck Rd, Casa Grande, Arizona, conducted by our investigator on March 15-16, 1999, confirmed that you offered animals for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

On or about September 28, 1998, you sold a culled dairy cow identified by USDA report #283606 for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of oxytetracycline in the liver at 12.00 ppm, in the muscle at 5.00 ppm and in the kidney at 31.00 ppm. Tolerances of 6 ppm in the liver, 2 ppm in the muscle and 12 ppm in the kidney have been established for residues of oxytetracycline in the edible tissues of cattle, Title 21 Code of Federal Regulations (CFR) 556.500.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack the conditions of an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

The following new animal drugs found on your premises are adulterated under Section 501(a)(5) of the Act, when they are used, by your firm, in a manner contrary to their approved labeling:

1. Injectable penicillin G procaine, such as durvet's Pen-Aqueous, is labeled for a dosage of 1 cc/100 lbs body weight. Your use of 2 cc/100 lbs of body weight is greater than labeled.

2. Amoxi-Mast, Pfizer's brand of amoxicillin intramammary tubes are labeled for administration of 1 tube per affected quarter. Your administration of 2 tubes per quarter is greater than labeled.

The above is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice.

Please note that it is not necessary for you to personally ship adulterated animals in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

If you need clarification or have questions concernng this matter please contact Barbara J. Rincon, Consumer Safety Officer at (949) 798-7739.

Your response should be directed to:

Thomas L. Sawyer
Compliance Director
U.S. Food & Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,

Elaine C. Messa
District Director
Los Angeles District